April 14, 2023

Plasmapp Co., Ltd.
% Candace Cederman
Consultant
CardioMed Device Consultants LLC
1783 Forest Drive, Suite 254
Annapolis, Maryland 21401

Re: K220345
Trade/Device Name: STERLINK mini Sterilizer with STERLOAD mini Cassette, Tyvek Roll with CI for STERLINK Sterilizer, Sterilization Process Indicator for STERLINK Sterilizer; Terragene Bionova SCBI (BT96), Terragene Bionova Reader Incubators (IC10/20FRLCD, Mini-Bio), Terragene Chemdye (CD42), Terragene Cintape (CT40)
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: Class II
Product Code: MLR, FRG, JOJ, FRC
Dated: February 25, 2022
Received: February 28, 2022

Dear Candace Cederman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Christopher K. Dugard -S

for Clarence W. Murray, III, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220345

Device Name

STERLINK mini Sterilizer with STERLOAD™ mini Cassette

Indications for Use *(Describe)*

The STERLINK mini sterilizer with STERLOAD™ mini cassette is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed, and dried reusable metal and nonmetal medical devices used in healthcare facilities. A pre-programmed sterilization lumen cycle operates at low pressure and low temperature and is thus suitable for processing medical devices sensitive to heat and moisture.

The STERLINK mini can sterilize*:

- Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
- Medical devices with a single stainless-steel lumen with:
  - o An inside diameter of 1.6 mm or larger and a length of 200 mm or shorter

*The validation testing was conducted using a maximum of five (5) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load with a total weight of 1.54 lbs.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K220345

Device Name
Tyvek® Roll with CI for STERLINK™ Sterilizer

Indications for Use *(Describe)*

Tyvek® Roll with CI for STERLINK™ Sterilizer, when used in CHAMBER mode, is intended to provide health care workers with an effective method to enclose devices intended for sterilization in the STERLINK™ sterilizer. The device is intended to allow sterilization of enclosed devices and also to maintain sterility of the enclosed devices until used up to 1 month post sterilization.

The materials compatible for use in the Tyvek® Roll with CI for STERLINK™ Sterilizer, when used in Chamber mode, are as follows: Aluminum 5052, Aluminum 6061, Stainless Steel 304, Stainless Steel 316L, Titanium, Acrylonitrile Butadiene Styrene (ABS), High Density Polyethylene (HDPE), Polypropylene (PP), Polytetrafluoroethylene (PTFE) and Silicone (Hardness 50).

The maximum load weight that can be placed in the Tyvek® roll is:
• 3.97 pounds (1.8 kg) for CHAMBER mode of FPS-15s Plus sterilizer
• 1.54 pounds (0.7 kg) for CHAMBER mode of STERLINK mini sterilizer

The roll is printed with a chemical indicator bar which is a process indicator (ISO 11140-1:2005) that changes from red to blue (or lighter) when exposed to hydrogen peroxide vapor during processing in the STERLINK™ sterilizer.

The Tyvek® Roll with CI for STERLINK™ Sterilizer is offered in the follow 1 type:
• Sterilization roll, Flat

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220345

Device Name

Sterilization Process Indicator for STERLINK™ Sterilizer
Terragene Bionova® SCBI (BT96), Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio), Terragene Chemdye® (CD42), Terragene Cintape® (CT40)

Indications for Use *(Describe)*

Terragene Bionova® SCBI (BT96) is a self-contained biological indicator inoculated with viable 10^6 Geobacillus stearothermophilus bacterial spores and is intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. BT96 has Super Rapid readout at 30 minutes at 60°C.

Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio) incubate at 60°C and 37°C and read the Terragene Bionova® SCBI for fluorescent results at the times prescribed in the User Manuals.

Terragene Chemdye® (CD42) is a chemical process indicator intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. The chemical indicator changes from red to yellow for CD42 to indicate that the conditions of the cycle have been met.

Terragene Cintape® (CT40) is a chemical process indicator tape intended for monitoring the efficacy of Vaporized Hydrogen Peroxide sterilization processes. The indicating tape changes from purple to green when exposure to vaporized hydrogen peroxide.

The self-contained biological indicator and chemical processing indicators are intended for use with:
• CHAMBER mode of FPS-15s Plus sterilizer
• CHAMBER mode of STERLINK mini sterilizer

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary – K220345

510(k) Summary
[as required by 21 CFR 807.92(c)]

STERLINK mini Sterilizer with STERLOAD™ mini Cassette
Tyvek® Roll with CI for STERLINK™ Sterilizer
Sterilization Process Indicator for STERLINK™ Sterilizer

510(k) K220345

General Information

Applicant/Submitter:	Plasmapp Co., Ltd. BVC-111, 125, Gwahak-ro, Yuseong-gu, Daejeon, 34141, Rep. of Korea (South Korea) Tel: +82 42 716 2115
Contact Person: Address:	Candace Cederman CardioMed Device Consultants LLC 1783 Forest Drive, Suite 254 Annapolis, MD 21401 Tel: +1 410 674 2060
Preparation Date:	April 13, 2023

Device Name and Code

Device Trade Name:	A. STERLINK mini Sterilizer with STERLOAD™ mini Cassette B. Tyvek® Roll with CI for STERLINK™ Sterilizer C. Sterilization Process Indicator for STERLINK™ Sterilizer; Terragene Bionova® SCBI (BT96); Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio); Terragene Chemdye® (CD42); Terragene Cintape® (CT40)
Common Name:	A. Vapor Phase Hydrogen Peroxide Sterilization System B. Tyvek® Roll for VH2O2 Sterilizer C. Self-contained Biological Indicator, Self-Contained Biological Indicator Incubator, Chemical Indicator.

510(k) Summary – K220345

Classification Name:	A. Ethylene Oxide Gas Sterilizer B. Sterilization Wrap C. Sterilization Process Indicator
Product Code:	A. MLR B. FRG, JOJ C. FRC, JOJ
Regulation Number:	A. 21 CFR 880.6860 B. 21 CFR 880.6850, 21 CFR 880.2800 3. 21 CFR 880.2800
Classification:	Class II
Review Panel:	General Hospital

A. STERLINK mini Sterilizer with STERLOAD™ mini Cassette

A.1 Device Description

The STERLINK mini sterilizer with STERLOAD™ mini cassette is a low temperature sterilizer which uses the STERLINK™ process to inactivate microorganisms on a broad range of medical devices and instruments. This sterilizer offers an effective, safe, fast, economical, easy to use, reliable, and flexible sterilization method.

This system consists of a main device connected pump module and cassette which are called the STERLINK mini and STERLOAD™ mini cassette, respectively. The STERLOAD™ mini cassette contains 58-59.5% (weight concentration) of hydrogen peroxide (H_2O_2) which is utilized as the sterilant.

A.2 Indications / Intended Use

The subject and predicate device have the same intended use. The specific indications for use differ only in the size and weight of the medical devices that can be sterilized in each chamber.

> The STERLINK mini sterilizer with STERLOAD™ mini cassette is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed, and dried reusable metal and nonmetal medical devices used in healthcare facilities. A pre-programmed

sterilization cycle operates at low pressure and low temperature and is thus suitable for processing medical devices sensitive to heat and moisture.

- The STERLINK mini can sterilize*:
  - Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
  - Medical devices with a single stainless-steel lumen with:
    - An inside diameter of 1.6 mm or larger and a length of 200 mm or shorter

*The validation testing for all lumen sizes was conducted using a maximum of five (5) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load with a total weight of 1.54 lbs.

A.3 Technical Characteristics in Comparison to Predicate Devices

A summary of the technical characteristics of the subject device and predicate device can be found in the table below.

	Subject Device	Predicate Device	Comparison
	Plasmapp Co., Ltd.	Plasmapp Co., Ltd.	Same
Device Name	STERLINK mini	FPS-15s Plus	-
510(k) Number	-	K212200	-
Device Classification Name	Ethylene oxide gas sterilizer	Ethylene oxide gas sterilizer	Same
Classification Product Code	MLR	MLR	Same
Regulation Number	21 CFR 880.6860	21 CFR 880.6860	Same
Intended Use	The STERLINK mini sterilizer with STERLOAD™ mini cassette is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed, and dried reusable metal and nonmetal medical devices used in healthcare facilities. A pre-programmed sterilization lumen cycle operates at low pressure and low temperature and is thus suitable for processing medical devices sensitive to heat and moisture. The STERLINK mini can sterilize*: • Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Medical devices with a single stainless-steel lumen with: o An inside diameter of 1.6 mm or larger and a length of 200 mm or shorter *The validation testing for all lumen sizes was conducted using a maximum of five (5) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The	The STERLINK™ FPS-15s Plus sterilizer with STERLOAD™ cassette is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed, and dried reusable metal and nonmetal medical devices used in healthcare facilities. A pre-programmed sterilization lumen cycle operates at low pressure and low temperature and is thus suitable for processing medical devices sensitive to heat and moisture. The STERLINK™ FPS-15s Plus can sterilize*: • Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Medical devices with a single stainless-steel lumen with: o An inside diameter of 2.4 mm or larger and a length of 280 mm or shorter *The validation testing for all lumen sizes was conducted using a maximum of five (5) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The	Similar; Intended Use is the same with the exception of the maximum load and lumen specification

	Subject Device	Predicate Device	Comparison
	Plasmapp Co., Ltd.	Plasmapp Co., Ltd.	Same
	validation studies were performed using a validation load with a total weight of 1.54 lbs.	validation studies were performed using a validation load with a total weight of 3.97 lbs.	
Physical Characteristic	Self-contained, stand-alone device	Self-contained, stand-alone device	Same
Design and Construction	Welded frame onto which is mounted the sterilization chamber along with a variety of instruments and components, and controls, piping, all of which is housed in covered frame as main sterilizer. The vacuum pump is housed in a frame with a cover and configured separately, and connected to the main sterilizer through a pumping pipe.	Welded frame onto which is mounted the sterilization chamber along with a variety of instruments and components, controls, piping, and vacuum pump, all of which is housed in covered frame	Same Components as Predicate with a different configuration
Chamber Volume	7 L	14 L	Smaller than Predicate
Weight	Main sterilizer: 44.1 lbs (20 kg) Pump module: 46.3 lbs (21 kg)	147 lbs (67 kg)	Lighter than Predicate
Max Power	1000 W	1000 W	Same
Control System	Embedded Linux	Embedded Linux	Same
Internal process monitor			
Temperature	Chamber and vaporizer thermocouple	Chamber and vaporizer thermocouple	Same
Pressure	Chamber pressure transducers	Chamber pressure transducers	Same
Sterilant Concentration	None	None	Same
Operational Principle	Sterilization of the intended devices by exposure under controlled conditions of pressure, temperature, and time	Sterilization of the intended devices by exposure under controlled conditions of pressure, temperature, and time	Same
Operational Parameters	Low pressure (vacuum; sub-atmospheric down to 3 Torr) and temperature (60°C)	Low pressure (vacuum; sub-atmospheric down to 3 Torr) and temperature (60°C)	Same
Pre-processing Requirements	Cleaned, rinsed, and dried devices	Cleaned, rinsed, and dried devices	Same

	Subject Device	Predicate Device	Comparison
	Plasmapp Co., Ltd.	Plasmapp Co., Ltd.	Same
Devices	Reusable metal and non-metal medical devices that are used in healthcare facilities, including those that are sensitive to heat and moisture	Reusable metal and non-metal medical devices that are used in healthcare facilities, including those that are sensitive to heat and moisture	Same
Sterilization Cycles	One (1) pre-programmed; approximately 18 minutes	One (1) pre-programmed; approximately 36 minutes	Similar; Shortened cycle compared to Predicate
Sterilant			
Model Name	STERLOAD™ mini	STERLOAD™	Different
Type	Cassette type (unit dose)	Cassette type (unit dose)	Same
Sterilant	58-59.5% aqueous solution of hydrogen peroxide	58-59.5% aqueous solution of hydrogen peroxide	Same
Shelf Life	12 months	12 months	Same
Monitoring accessories*			
Biological Indicator	Self-contained biological indicator, *Geobacillus stearothermophilus*	Self-contained biological indicator, *Geobacillus stearothermophilus*	Same
Process Challenge Device / Routine Test Pack	Self-contained biological indicator, *Geobacillus stearothermophilus*	Self-contained biological indicator, *Geobacillus stearothermophilus*	Same
Chemical Indicator	Terragene® CI Strips and Tapes	Terragene® CI Strips and Tapes	Same
Miscellaneous (Sterilization wrap)*			
Load Packaging	Tyvek® and PET/LLDPE film	Tyvek® and PET/LLDPE film	Same

***** Denotes revision made to correct manufacturing material (previously listed as Tyvek®/HDPE)

Technological differences between the STERLINK mini sterilizer and the predicate device are minimal and include:

- The STERLINK mini sterilizer has a smaller sterilization chamber volume, which is lighter and requires separated pump module.

A.4 Performance Data

The non-clinical tests performed are listed in the table below.

Test	Purpose	Acceptable criteria	Result
Human factors and usability engineering	To confirm whether the user error affects the risk to user safety and performance of the device when the device is used according to the intended use in accordance with IEC 62366-1	User safety risk and device performance degradation due to user errors should not occur.	Pass
Biocompatibility	To confirm the biological safety of the sterilized load in accordance with ISO 10993-5.	≦ Grade 2	Pass
Software validation	To verify that the software is compatible for the intended use of the device in accordance with IEC 62304	The risk of all identified software hazards should be reduced to an acceptable risk level and the device is appropriate for its intended use.	Pass
Electrical safety	To confirm the electrical safety of the device in accordance with IEC 60601-1, IEC 61010-1, and IEC 61010-2-040	The device conforms to the relevant standards.	Pass
Electromagnetic compatibility (EMC)	To confirm the electromagnetic wave safety of the device in accordance with IEC 60601-1-2 and EN 55011	The device conforms to the relevant standards.	Pass
Resistance validation for biological indicator test	To validate the D-value and total kill endpoint of the biological indicators in accordance with ISO 11138-1	The total kill endpoint time should be shorter than the sterilization half cycle.	Pass
Lumen sterilization	To confirm the lumen sterilization performance in accordance with ISO 14937	The SAL (Sterility Assurance Level) should be at least 10^{-6}.	Pass
Surface sterilization	To confirm the surface sterilization performance of various materials in accordance with ISO 14937, ISO 11737-1, and ISO11737-2.	The SAL (Sterility Assurance Level) should be at least 10^{-6}.	Pass
Mated surface sterilization	To confirm the mated surface sterilization performance of various materials in accordance with ISO 14937, ISO 11737-1, and ISO11737-2.	The SAL (Sterility Assurance Level) should be at least 10^{-6}.	Pass
Simulated use test	To demonstrate the efficacy of the sterilization validation on medical devices contaminated by organic and inorganic matters with bacterial spores in accordance with ASTM E1837-96 and ISO 11737-1.	The microorganisms should not survive after sterilization.	Pass
In-use test	To demonstrate the sterilization validation of the used and clinically pretreated medical devices in accordance with ASTM E1837-96	The microorganisms should not survive after sterilization.	Pass
Sporicidal activity test	To confirm the sporicidal activity of the device in accordance with AOAC Official Method 966.04	All spores inoculated on the carriers must be sterilized.	Pass
Bacteriostasis test	To confirm the bacteriostasis action of sterilized various materials after sterilization process in accordance with ISO 11737-1	Sterilized materials should not exhibit the bacteriostatic effects.	Pass
Material compatibility test	To demonstrate the compatibility of various materials in the sterilization cycle in accordance with ASTM D638, ASTM E8/E8M, ASTM D790, ASTM E290-14, ASTM D256, ASTM E23-18, ASTM E1164, ASTM D3985, and ASTM F1249	The physical properties of the material after sterilization should be similar to those before sterilization.	Pass

Test	Purpose	Acceptable criteria	Result
Delivery validation	To validate the packaging and performance of the device after exposure to simulated shipping conditions in accordance with ASTM D4169-14.	After the distribution cycle of the drop test, significant deformations and defects in the electrical and mechanical performance of the device should not be observed.	Pass
Hydrogen peroxide gas detection test	To measure the concentration of the hydrogen peroxide emitted from the device in accordance with Occupational Safety and Health Administration (OSHA, TWA).	< 1 ppm hydrogen peroxide gas detection	Pass
Sterilant preservation test	To verify the shelf life of the sterilant cassette in accordance with the internal test standard.	The sterilant should meet the specified weight, concentration, and pH standards during the shelf life.	Pass

B. Tyvek® Roll with CI for STERLINK™ Sterilizer

B.1 Device Description

Tyvek® Roll with CI for STERLINK™ Sterilizer is intended to be used to contain medical devices to be terminally sterilized in the STERLINK™ sterilization system. The medical devices are inserted into the roll, sealed, and then sterilized in the STERLINK™ sterilization system. After completion of the sterilization process, the roll maintains sterility of the enclosed medical devices until the seal is opened. The device is intended to allow sterilization of enclosed devices and also to maintain sterility of the enclosed devices for up to 1 month post sterilization.

The roll is printed with a chemical indicator bar that changes from red to blue (or lighter) when exposed to hydrogen peroxide vapor during processing in the STERLINK™ sterilizer.

The Tyvek® Roll with CI for STERLINK™ Sterilizer is offered in one type as a Flat Sterilization roll. The sterilization roll is made from a Tyvek® sheet and a clear plastic film that are heat sealed together on opposite two sides. After being cut into a suitable length, the product to be sterilized is placed inside and the two open ends are heat sealed. The process indicator printed on the Tyvek® will exhibit a color change after the roll is exposed to hydrogen peroxide (H_2O_2).

B.2 Indications / Intended Use

The subject and predicate device have the same intended use. The specific indications for use differ only in the identification of the appropriate sterilization cycles and the weight of the medical devices that can be sterilized in each chamber. The revised indications for use are as follows:

> Tyvek® Roll with CI for STERLINK™ Sterilizer, when used in CHAMBER mode, is intended to provide health care workers with an effective method to enclose devices intended for sterilization in the STERLINK™ sterilizer. The device is intended to allow sterilization of enclosed devices and also to maintain sterility of the enclosed devices until used up to 1 month post sterilization.
>
> The materials compatible for use in the Tyvek® Roll with CI for STERLINK™ Sterilizer, when used in CHAMBER mode, are as follows: Aluminum 5052, Aluminum 6061, Stainless Steel 304, Stainless Steel 316L, Titanium, Acrylonitrile Butadiene Styrene (ABS), High Density Polyethylene (HPDE), Polypropylene (PP), Polytetrafluorethylene (PTFE) and Silicone (Hardness 50).

The maximum load weight that can be placed in the Tyvek® roll is:

- 3.97 pounds (1.8 kg) for CHAMBER mode of FPS-15s Plus sterilizer
- 1.54 pounds (0.7 kg) for CHAMBER mode of STERLINK mini sterilizer

The roll is printed with a chemical indicator bar which is a process indicator (ISO 11140-1:2005) that changes from red to blue (or lighter) when exposed to hydrogen peroxide vapor during processing in the STERLINK™ sterilizer.

The Tyvek® Roll with CI for STERLINK™ Sterilizer is offered in the follow 1 type:

- Sterilization roll, Flat

B.3 Technical Characteristics in Comparison to Predicate Devices

A summary of the technical characteristics of the subject device and predicate device can be found in the table below.

	Subject Device	Predicate Device	Comparison
510(k) Sponsor	Plasmapp Co., Ltd.	Plasmapp Co., Ltd.	Same
Manufacturer	Sigma Medical Supplies Corp.	Sigma Medical Supplies Corp.	Same
Device Name	Tyvek® Roll with CI for STERLINK™ Sterilizer	Tyvek® Roll with CI for STERLINK™ Sterilizer	Same
510(k) Number	-	K212198	-
Device Classification Name	1) Sterilization Wrap 2) Sterilization Process Indicator	1) Sterilization Wrap 2) Sterilization Process Indicator	Same
Classification Product Code	1) FRG 2) JOJ	1) FRG 2) JOJ	Same
Regulation Number	1) 21 CFR 880.6850 2) 21 CFR 880.2800	1) 21 CFR 880.6850 2) 21 CFR 880.2800	Same
Intended Use	Tyvek® Roll with CI for STERLINK™ Sterilizer, when used in CHAMBER mode, is intended to provide health care workers with an effective method to enclose devices intended for sterilization in the STERLINK™ sterilizer. The device is intended to allow sterilization of enclosed devices and also to maintain sterility of the enclosed devices until used up to 1 month post sterilization. The materials compatible for use in the Tyvek® Roll with CI for STERLINK™ Sterilizer, when used in Chamber mode, are as follows: Aluminum 5052, Aluminum 6061, Stainless Steel 304, Stainless Steel 316L, Titanium, Acrylonitrile Butadiene Styrene (ABS), High Density Polyethylene (HDPE), Polypropylene (PP), Polytetrafluoroethylene (PTFE) and Silicone (Hardness 50).	Tyvek® Roll with CI for STERLINK™ Sterilizer, when used in CHAMBER mode, is intended to provide health care workers with an effective method to enclose devices intended for sterilization in the STERLINK™ sterilizer. The device is intended to allow sterilization of enclosed devices and also to maintain sterility of the enclosed devices until used up to 1 month post sterilization. The materials compatible for use in the Tyvek® Roll with CI for STERLINK™ Sterilizer, when used in Chamber mode, are as follows: Aluminum 5052, Aluminum 6061, Stainless Steel 304, Stainless Steel 316L, Titanium, Acrylonitrile Butadiene Styrene (ABS), High Density Polyethylene (HDPE), Polypropylene (PP),	Similar; Intended Use Expanded to include additional device and its operating mode

	Subject Device	Predicate Device	Comparison
	The maximum load weight that can be placed in the Tyvek® roll is: • 3.97 pounds (1.8 kg) for CHAMBER mode of FPS-15s Plus sterilizer • 1.54 pounds (0.7 kg) for CHAMBER mode of STERLINK mini sterilizer The roll is printed with a chemical indicator bar which is a process indicator (ISO 11140-1:2005) that changes from red to blue (or lighter) when exposed to hydrogen peroxide vapor during processing in the STERLINK™ sterilizer. The Tyvek® Roll with CI for STERLINK™ Sterilizer is offered in the follow 1 type: • Sterilization roll, Flat	Polytetrafluoroethylene (PTFE) and Silicone (Hardness 50). The maximum load weight that can be placed in the Tyvek® roll is 3.97 lbs (1.8 kg). The roll is printed with a chemical indicator bar which is a process indicator (ISO 11140-1:2005) that changes from red to blue (or lighter) when exposed to hydrogen peroxide vapor during processing in the STERLINK™ sterilizer. The Tyvek® Roll with CI for STERLINK™ Sterilizer is offered in the follow 1 type: • Sterilization roll, Flat	
Pouch Types	Sterilization roll, Flat	Sterilization roll, Flat	Same
Device models (Configurations /Dimensions)	Mode: FR400100 Dimensions: 400mm x 100M	Mode: FR400100 Dimensions: 400mm x 100M	Same
Material Composition	Tyvek®, PET, PE, Water, CH_3COOH, Alcohol, n-Heptane adhesive, Hydrogen peroxide vapor Process Indicator Print Ink	Tyvek®, PET, PE, Water, CH_3COOH, Alcohol, n-Heptane adhesive, Hydrogen peroxide vapor Process Indicator Print Ink	Same
Sterilization Cycle	STERLINK™ FPS-15s Plus - Chamber mode (overall cycle: 36 minutes) STERLINK mini - Chamber mode (overall cycle: 18 minutes)	STERLINK™ FPS-15s Plus - Chamber mode (overall cycle: 36 minutes)	Similar; Expanded to include additional device and its operating mode
Design Feature	**Sterilization roll, Flat:** This roll is made from a Tyvek® and plastic film that are heat sealed on	**Sterilization roll, Flat:** This roll is made from a Tyvek® and plastic film that are heat sealed on	Same

	Subject Device	Predicate Device	Comparison
	opposite two sides. It will be cut into the suitable length and the opened sides will be heat-sealed. The indicators printed on the Tyvek® are the same with the self-sealing sterilization roll.	opposite two sides. It will be cut into the suitable length and the opened sides will be heat-sealed. The indicators printed on the Tyvek® are the same with the self-sealing sterilization roll.	
Chemical Indicator Device Design	The color of the Chemical Indicator changes from red to blue (or lighter) when exposed to hydrogen peroxide.	The color of the Chemical Indicator changes from red to blue (or lighter) when exposed to hydrogen peroxide.	Same
Shelf Life	28 months for STERILINK mini – Chamber mode 15 months for STERILINK FPS-15s Plus – Chamber mode	15 months for STERILINK FPS-15s Plus – Chamber mode	Similar; Expanded to include additional device and its operating mode

B.4 Performance data

The non-clinical tests performed are listed in the table below.

Performance Test	Purpose	Acceptable criteria	Result
Sterilization efficacy test	To ensure that the device is suitable for the sterilization process in accordance with ISO 14937.	The SAL should be at least 10^{-6}.	Pass
CI of sterilization roll validation	To confirm that the shelf life before and after the sterilization of device, and to ensure CI of the device is compatible for the sterilization process in accordance with ANSI/AAMI/ISO 11140-1.	- CI should not change completely with temperature, and sterilant exposure time of less than 7 seconds, during the shelf life. - CI should maintain the changed color after real-time aging during shelf life after sterilization.	Pass
Internal pressurization test	To verify the internal pressurization of the sterilized device at the shelf life in accordance with ASTM F1980-16 and ASTM F1140/F1140M-13.	- Burst pressure: ≧ 1kPA - Creep time: > 30 sec in creep pressure (> 80% of burst pressure)	Pass
Visual inspection test	To confirm the sterilized device integrity was maintained at shelf life in accordance with ASTM F1980-16 and ASTM F1886/F1886M-16.	There should be no defects in the sealing area.	Pass

Performance Test	Purpose	Acceptable criteria	Result
Dye penetration test	To confirm the packaging of the sterilized device was maintained at shelf life in accordance with ASTM F1980-16 and ASTM F1929-15.	There should be no dye leakage.	Pass
Tensile strength of Tyvek®	To confirm the physical properties of the sterilized device at shelf life in accordance with ASTM F1980-16, ASTM D5035-11, ASTM D882, ASTM F88, and ASTM D1922-20.	The physical properties must meet the criteria specified by the manufacturer.	Pass
Tensile strength of plastic film			Pass
Seal strength			Pass
Tear resistance			Pass
Microbial Barrier Test	To confirm the microbial barrier performance of sterilized devices at shelf life in accordance with ASTM F1980-16 and DIN 58953-6.	- Test with liquid inoculum : No microbial growth should appear. - Test with gas inoculum : Only a maximum 15 colonies should grow out of a total of 10 bacterial permeability testers. The number of colonies in each bacterial permeability tester should not be greater than five.	Pass
Residual sterilant on Tyvek® validation	To confirm the time required for the residual sterilant to be reduced to a safe amount after sterilization in accordance with the internal test standard.	≦ 0.05 ppm	Pass
Biocompatibility test	To confirm the biological safety after sterilization in accordance with ISO 10993-5	≦ Grade 2	Pass

C. Sterilization Process Indicator for STERLINK™ Sterilizer

C.1 Device Description

Terragene® Bionova® BT96 Fluorescence Super Rapid Readout Biological Indicators are single-use Self-Contained Biological Indicators (SCBIs) that consist of a polypropylene tube, a spore carrier, and a glass ampoule with a culture medium, enclosed with a colored cap. Each tube contains a population of *Geobacillus stearothermophilus* ATCC 7953 spores inoculated on a spore carrier, a plastic cap with holes and a barrier permeable to Plasma or Vaporized Hydrogen Peroxide. Each BT96 has a Process Indicator on label that changes from purple to green when exposed to hydrogen peroxide. The Bionova® BT96 Biological Indicators have been designed for monitoring of Vaporized Hydrogen Peroxide sterilization processes when used in conjunction with Bionova® IC10/20FRLCD or MiniBio Auto-Readers Incubators.

Chemdye® CD42 Process Indicators (Type 1 according to ISO 11140-1:2014 standard) are single-use chemical indicators that consist of plastic strips printed with indicator ink. These indicators have been designed to monitor Plasma or Vaporized Hydrogen Peroxide sterilization processes within loads, ensuring an adequate exposure to the sterilizing agent during the sterilization process and allowing to distinguish between processed and unprocessed items.

Cintape® CT40 Process Indicators (Type 1 according to ISO 11140-1:2014 standard) are single-use chemical indicators that consist of a roll of self-adhesive plastic tape printed with indicator ink. These indicators have been designed to monitor Plasma or Vaporized Hydrogen Peroxide sterilization processes, ensuring an adequate exposure to the sterilizing agent during the sterilization process and allowing to distinguish between processed and unprocessed items.
The adhesive component of the tape allows the adhesion to different types of packaging and wraps, such as cloth, paper and plastic.

C.2 Indications for Use / Intended Use

The subject and predicate device have the same intended use. The specific indications for use differ only in the identification of the appropriate sterilization cycles. The revised indications for use are as follows:

> Terragene Bionova® SCBI (BT96) is a self-contained biological indicator inoculated with viable 10^6 *Geobacillus stearothermophilus* bacterial spores and is intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. BT96 has Super Rapid readout at 30 minutes at 60°C.

Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio) incubate at 60°C and 37°C and read the Terragene Bionova® SCBI for fluorescent results at the times prescribed in the User Manuals.

Terragene Chemdye® (CD42) is a chemical process indicator intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. The chemical indicator changes from red to yellow to indicate that the conditions of the cycle have been met.

Terragene Cintape® (CT40) is a chemical process indicator tape intended for monitoring the efficacy of Vaporized Hydrogen Peroxide sterilization processes. The indicating tape changes from purple to green when exposure to vaporized hydrogen peroxide.

The self-contained biological indicator and chemical processing indicators are intended for use with:

- CHAMBER mode of FPS-15s Plus sterilizer
- CHAMBER mode of STERLINK mini sterilizer

C.3 Technical Characteristics in Comparison to Predicate Devices

A summary of the technical characteristics of the subject device and predicate device can be found in the table below.

	Subject Device	Predicate Device	Comparison
Sponsor	Plasmapp Co., Ltd.	Plasmapp Co., Ltd.	Same
Device Name	Sterilization Process Indicator for STERLINK™ Sterilizer Terragene Bionova® SCBI (BT96); Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio); Terragene Chemdye® (CD42); Terragene Cintape® (CT40)	Terragene Bionova® SCBI (BT96); Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio); Terragene Chemdye® (CD42); Terragene Cintape® (CT40)	Same
510(k) Number	-	K212193	-
Manufacturer	Terragene® S.A.	Terragene® S.A.	Same
Device Classification Name	Sterilization Process Indicator	Sterilization Process Indicator	Same
Classification Product Code	FRC (biological indicators) JOJ (chemical indicators)	FRC (biological indicators) JOJ (chemical indicators)	Same
Regulation Number	21 CFR 880.2800	21 CFR 880.2800	Same

<table>
<tr><th></th><th>Subject Device</th><th>Predicate Device</th><th>Comparison</th></tr>
<tr><td>Indications for Use</td><td>Terragene Bionova® SCBI (BT96) is a self-contained biological indicator inoculated with viable 10^6 Geobacillus stearothermophilus bacterial spores and is intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. BT96 has Super Rapid readout at 30 minutes at 60ºC.

Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio) incubate at 60ºC and 37ºC and read the Terragene Bionova® SCBI for fluorescent results at the times prescribed in the User Manuals.

Terragene Chemdye® (CD42) is a chemical process indicator intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. The chemical indicator changes from red to yellow for CD42 to indicate that the conditions of the cycle have been met.

Terragene Cintape® (CT40) is a chemical process indicator tape intended for monitoring the efficacy of Vaporized Hydrogen Peroxide sterilization processes. The indicating tape changes from purple to green when exposure to vaporized hydrogen peroxide.

The self-contained biological indicator and chemical processing indicators are intended for use with:
• CHAMBER mode of FPS-15s Plus sterilizer
• CHAMBER mode of STERLINK mini sterilizer</td><td>Terragene Bionova® SCBI (BT96) is a self-contained biological indicator inoculated with viable 10^6 Geobacillus stearothermophilus bacterial spores and is intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. BT96 has Super Rapid readout at 30 minutes at 60ºC.

Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio) incubate at 60ºC and 37ºC and read the Terragene Bionova® SCBI for fluorescent results at the times prescribed in the User Manuals.

Terragene Chemdye® (CD42) is a chemical process indicator intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. The chemical indicator changes from red to yellow for CD42 to indicate that the conditions of the cycle have been met.

Terragene Cintape® CT40 is a chemical process indicator tape intended for monitoring the efficacy of Vaporized Hydrogen Peroxide sterilization processes. The indicating tape changes from purple to green when exposure to vaporized hydrogen peroxide.

The self-contained biological indicator and chemical processing indicators are intended for use with the STERLINK™ FPS-15s Plus when operating in chamber mode.</td><td>Similar; Expanded to include additional device and its operating mode</td></tr>
<tr><td>Intended Use: Cycles</td><td><table><tr><th colspan="2">Vaporized Hydrogen Peroxide</th></tr><tr><th>Models</th><th>Cycle</th></tr><tr><td rowspan="2">BT96, CD42, CT40</td><td>STERLINK™ FPS-15s Plus - Chamber mode</td></tr><tr><td>STERLINK mini - Chamber mode</td></tr></table></td><td><table><tr><th colspan="2">Vaporized Hydrogen Peroxide</th></tr><tr><th>Models</th><th>Cycle</th></tr><tr><td>BT96, CD42, CT40</td><td>STERLINK™ FPS-15s Plus - Chamber mode</td></tr></table></td><td>Similar; Expanded to include additional device and its operating mode</td></tr>
</table>

	Subject Device	Predicate Device	Comparison
Terragene Bionova® SCBI (BT96)			
Type of Biological Indicator	Self-Contained	Self-Contained	Same
Organism Spore Species Strain	*Geobacillus stearothermophilus* ATCC 7953 spores inoculated on a strip (spore carrier)	*Geobacillus stearothermophilus* ATCC 7953 spores inoculated on a strip (spore carrier)	Same
Viable Spore Population	$\geq 10^6$	$\geq 10^6$	Same
Resistance characteristics	*D*-value Survival time/Kill window	*D*-value Survival time/Kill window	Same
Intended Sterilization Cycles	STERLINK™ FPS-15s Plus - Chamber mode (overall cycle: 36 minutes) STERLINK mini - Chamber mode (overall cycle: 18 minutes)	STERLINK™ FPS-15s Plus - Chamber mode (overall cycle: 36 minutes)	Similar; Expanded to include additional device and its operating mode
Shelf Life	2 years	2 years	Same
Terragene Chemdye® (CD42), Terragene Chemdye® (CT40)			
Intended Sterilization Cycles	STERLINK™ FPS-15s Plus - Chamber mode (overall cycle: 36 minutes) STERLINK mini – Chamber mode (overall cycle: 18 minutes)	STERLINK™ FPS-15s Plus – Chamber mode (overall cycle: 36 minutes)	Similar; Expanded to include additional device and its operating mode
Device design	Strip, Tape	Strip, Tape	Same
Color Change upon Exposure to H_2O_2	CD42: red to yellow CT40: purple to green	CD42: red to yellow CT40: purple to green	Same
Recommended Storage Conditions	Dry place, away from sunlight, at temperature between 10-30ºC, 30-80% relative humidity. Do not wet. Do not store close to sterilizing agents.	Dry place, away from sunlight, at temperature between 10-30ºC, 30-80% relative humidity. Do not wet. Do not store close to sterilizing agents.	Same
Shelf Life	5 years	5 years	Same

The subject and predicate devices are identical with respect to the organism, accessories, spore population, resistance characteristics, culture conditions, carrier materials, packaging, storage conditions and claimed shelf life. The only difference between the subject and predicate devices

are the proposed indications for use, to label the indicators for use with the STERILINK mini when operating in chamber mode.

C.4 Performance Data

The non-clinical tests performed are listed in the table below.

Item	Test	Purpose	Acceptable criteria	Result
Self-Contained Biological Indicator (BT96)	Resistance validation for biological indicator test	To validate the D-value and total kill endpoint of biological indicators in accordance with ISO 11138-1.	The total kill endpoint time should be shorter than the half cycle sterilant exposure time.	Pass
	BI & Test pack validation test	To verify the suitability of the test pack to be used as monitoring of the sterilization process in accordance with the internal test standard.	The test pack with SCBI should fail to sterilize in half cycle and succeed in full cycle.	Pass
Chemical Indicator (CD42, CT40)	Performance characteristics obtained from resistometer	To evaluate the correct performance of chemical indicators, by testing them at different exposure conditions in accordance with ANSI/AAMI/ISO 11140-1.	The CI should change color correctly only when exposed to the temperature and sterilant concentration conditions specified by the manufacturer	Pass
	Biocompatibility	To demonstrate that the CI does not offset or transfer during and after the sterilization process in accordance with ANSI/AAMI/ISO 11140-1.	The CI does not release any substance or bleed when the sterilization process.	Pass
	Endpoint stability	To demonstrate the stability of the endpoint reaction of CI at the end of their shelf life and specified period after sterilization in accordance with ANSI/AAMI/ISO 11140-1.	The endpoint reaction of CI should be maintained until the shelf life and specified period after sterilization.	Pass
	Shelf life study	To verify the shelf life of the CI in accordance with ANSI/AAMI/ISO 11140-1.	The endpoint reaction of the real time aged CI should be maintained until shelf life.	Pass
	Chemical indicator validation	To confirm the compatibility of the CI for the sterilization process in accordance with the internal test standard	The minimum time required for color change of CI within the sterilization process time should be confirmed.	Pass

Clinical Data

This submission does not contain any data from clinical testing

Conclusions

The conclusions drawn from the nonclinical tests demonstrate that the subject devices, STERLINK mini Sterilizer with STERLOAD mini Cassette, Tyvek Roll with CI for STERLINK Sterilizer, and Sterilization Process Indicator for STERLINK Sterilizer: Terragene Bionova SCBI (BT96), Terragene Bionova Reader Incubators (IC10/20FRLCD, Mini-Bio), Terragene Chemdye (CD42) and Terragene Cintape (CT40) are as safe, as effective, and perform as well as or better than the legally marketed predicate devices, STERLINK FPS-15s Plus Sterilizer with STERLOAD™ Cassette, Tyvek® Roll with CI for STERLINK™ Sterilizer, and Terragene Bionova® SCBI (BT96), Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio), Terragene Chemdye® (CD42), Terragene Cintape® (CT40).